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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,305	10/17/2003	Martin P. Vacanti	VAC 106	8886

23579 7590 05/29/2007

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EXAMINER	
DAVIS, RUTH A	

ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
05/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/688,305	VACANTI ET AL.	
	Examiner	Art Unit	
	Ruth A. Davis	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) *1-17 and 23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-22 and 33* is/are rejected.

7)☒ Claim(s) *24-32* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response filed on January 23, 2007 has been received and previously entered into the case as indicated in the Advisory Action mailed on February 13, 2007. Claims 1 – 33 are pending; claims 1 – 17 and 23 are withdrawn from consideration; claims 18 – 22 and 24 – 33 have been considered on the merits. All arguments have been fully considered.

Election/Restrictions

1. Claim 24 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

As such, the species election requirement between claims 25 – 31, set forth in the Office action mailed on February 24, 2006 has been reconsidered. **The species election requirement is hereby withdrawn as to any claim that requires all the limitations of an allowable claim.** Claims 26 – 27 and 29 - 31, directed to cell samples are no longer withdrawn from consideration because the claim(s) requires all the limitations of an allowable claim. However, claims 1 – 17 and 23, directed to methods for using a biological matrix are withdrawn from consideration because the claims do not require all the limitations of an allowable claim.

In view of the above noted withdrawal of the restriction requirement, applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may

be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Once a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claim Objections

2. Claims 24 – 32 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 33 is rendered vague and indefinite for reciting "further comprising" because the method of claim 24 recites a method "consisting essentially of". The phrase "further

comprising" broadens the scope of the claim from which it depends, making the scope of the claimed invention indefinite.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 18 – 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Vacanti et al. (US 5716404).

Applicant claims a living biological matrix comprising a cell, cell fragments, lipids and polysaccharides, wherein the matrix is made by a method consisting essentially of obtaining a cell sample, disrupting the sample to create a mixture containing cells and cellular debris, culturing the mixture while retaining the debris for a time sufficient to form a living biological matrix, and separating the biological matrix from the medium. The matrix further comprises a component that adds shape, structure, or support to the matrix; a hydrogel or adhesive; an antibiotic; and a cellular component selected from fibronectin, laminin, collagen, glycoprotein, thrombospondin, elastin, fibrillin, mucopolysaccharide, glycolipid, heparin sulfate, chondroitin sulfate, keratin sulfate, glycosaminoglycan, and hyaluronic acid.

Vacanti teaches a biological matrix comprising mesenchymal cells (undifferentiated, precursor cells, or spore like cells) that are dissociated (or has cell fragments, lipids and

polysaccharides) (abstract, col.2-3), struts (a component that adds shape, structure, support) (col.8-9) and a hydrogel (col.3-4). The matrix further includes cellular components such as fibrin, hyaluronic acid, collagen (col.4), fibronectin, laminin or glycosaminoglycans (col.8). Vacanti teaches the matrix is obtained by taking autologous cells (obtained from the recipient) and disrupting the cells via digestion the culturing the cells to form a matrix (col.2-3).

Although the reference does not specifically identify that the matrix is "living", the matrix of the prior art is the same as claimed by applicant. Thus the matrix of the art must also be a living matrix.

Although Vacanti does not specifically identify the method by which the matrix is obtained, the claim is considered to be a product by process claim. Thus, the patentability of a product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113)

7. Claims 18 – 19 and 21 – 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Vacanti et al. (US 588610).

Applicant claims a living biological matrix comprising a cell, cell fragments, lipids and polysaccharides, wherein the matrix is made by a method consisting essentially of obtaining a cell sample, disrupting the sample to create a mixture containing cells and cellular debris,

culturing the mixture while retaining the debris for a time sufficient to form a living biological matrix, and separating the biological matrix from the medium. The matrix further comprises a component that adds shape, structure, or support to the matrix; an antibiotic; and a cellular component selected from fibronectin, laminin, collagen, glycoprotein, thrombospondin, elastin, fibrillin, mucopolysaccharide, glycolipid, heparin sulfate, chondroitin sulfate, keratin sulfate, glycosaminoglycan, and hyaluronic acid.

Vacanti teaches a biological matrix comprising parenchymal cells (undifferentiated, precursor cells, or spore like cells) that are dissociated (or has cell fragments, lipids and polysaccharides) (col.2-3), struts (a component that adds shape, structure, support) (col.5), cellular components such as collagen, fibronectin, laminin or glycosaminoglycans (col.5). The matrix further comprises antibiotics (examples). Vacanti teaches the matrix is obtained by taking autologous cells (obtained from the recipient) and disrupting the cells via digestion the culturing the cells to form a matrix (col.6).

Although the reference does not specifically identify that the matrix is "living", the matrix of the prior art is the same as claimed by applicant. Thus the matrix of the art must also be a living matrix.

Although Vacanti does not specifically identify the method by which the matrix is obtained, the claim is considered to be a product by process claim. Thus, the patentability of a product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly

different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113)

Response to Arguments

Applicant argues that the references do not teach the method by which the matrix is obtained, that those of the prior art require enzymatic digestion then cell culture, that the references do not teach digestion of cells or including cellular debris in the culture, and that the references use polymeric fibers as the mesh which are exogenous.

However, these arguments fail to persuade because as stated above, the process limitations are considered to be product by process limitations. Moreover, the patentability of a product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper.

Regarding applicant's assertions that the references use an exogenous polymeric matrix, it is noted that the claims recite the biological matrix comprises a component that adds shape, structure or support. Moreover, the claims do not exclude exogenous supports. Thus, the argument is not commensurate in scope with the claimed invention.

Allowable Subject Matter

8. Claims 24 – 32 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-F 7:00 -3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ruth A. Davis/
Primary Examiner
Art Unit 1651

May 24, 2007